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APPLICATION NUMBER: *60/513,696*
FILING DATE: *October 24, 2003*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

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J shua	Gur	Jerusalem Israel

☐ Additional inventors are being named on the ___ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

Tonometer

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ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification Number of Pages 10 ☐ CD(s), Number ____

☒ Drawing(s) Number of Sheets 5 ☐ Other (specify) ____

☐ Application Data Sheet. See 37 CFR 1.76

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☐ No.

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Respectfully submitted,

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Provisional Application for a patent

10/10/2003

Cover page

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Title of invention:

Device for measurement of intra ocular pressure

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US Government agency that has a property interest

None

Background of the invention

The medical significance of measurement of the hydrostatic intra-ocular pressure (IOP) is well known in the science of eye medicine. Internal eye pressure is a cause of Glaucoma and other eye diseases.

Measurement of IOP is performed by professional MD's, using a variety of methods – mainly the indentation tonometry, the applanation tonometry and the non-cotact tonometry. An example of the indentation tonometry is the Schiotz Tonometer from the 1930's. A recent one is the Mentor Tono-Pen XL from Mentor O&O, Inc. Norwell, Ma US. An example of the Applanation tonometry is the Goldman Tonometer, which is a standard Tonometer in many medical institutions. An example of the non-contact tonometry is the puff Tonometer XPERT NCT from Reichert Cambridge US.

Once a user is diagnosed as having an excessive eye pressure, it is often important to monitor the eye pressure periodically – typically once or twice a week.

It is very desirable that a user will be able to measure his or her own IOP at home, and not need to pay a special visit to the clinic for this purpose.

Home medicine knows a variety of medical measurement devices, such as thermometer, blood pressure and glukometers – but currently there is no practical solution for a reliable, accurate and inexpensive measurement o IOP at home.

Some solutions have been developed for this purpose, such as ultrasound method by which a gauge is pushed against the eyelid and the force is measured. The distances are determined by the ultrasound instrument thus providing the pressure. In another method the phosphene seen when a gauge is pushed aginst the eyelid gives a measure of the pressure. These solutions are less than desirable. The main problem in both of these methods is that the measurement is done through the eyelid, which introduces unknown contribution to the force of the eyelid, and tends to cause large inaccuracy in the measurement yielding non-useful results. It is the purpose of the current example to disclose an inexpensive, reliable and accurate device for home-measurement of IOP.

Definition of the invention

The present invention is based on a well-known and practiced technique for measurement of IOP, known in the art as "Puffer". Devices that are based on this technique are, for example the Reichart model XPERT NTC. The technology is very stable and well documented, and its earliest patents are as old as 26 years.

The present invention implements innovative means to enable the puff technique to be implemented in a home-IOP meter.

One technique is a non-imaging optics that does not need focusing of an image on the cornea.

The other technique is a co-axial light conduction, in which the light is projected and collected from the exact same direction.

These two techniques allow a relatively large tolerance in the distance between the device and the cornea, making the operation of the device feasible to a lay-user such as the user.

The general shape of the device is of a pair of eyeglasses that the user puts on for the purpose of measurement. The frame of the eyeglasses positions a measurement device in a close proximity to the eye (or two devices – one for each eye). The user then has to direct their eyesight to a clear optical target in the device, and press a single button. The device then sends a pulse of air through a tube onto the cornea, temporarily changing its curvature. A light beam is projected onto the cornea through an optical pipe, and some of the reflected light is collected by a detector through an optical conducting sleeve working in total internal reflection. The measurement of the dynamic changes in the amount of collected light reflected from the cornea, as the cornea is changing its shape, are indicative of the IOP, and a precise assessment of the IOP is determined by analyzing the dynamics of the reflected optical signal.

The invention will be understood better in the following detailed description of the drawings.

Drawings:

Figure 1 illustrates a general view of the device of the present invention

Figure 2 illustrates a detailed view of the optical subsystem of the device

Figure 3A-3E illustrate the time signals involved in the present invention

Figure 4 illustrates a general block diagram of the device of the present invention.

Figure 5 illustrates the general view of the Tonometer.

Detailed description of the drawings:

Attention is now called to Figure 1.

An eye 2 of a user is being tested for IOP by the system of the present invention. The IOP has to be measured in the area of the cornea 6, preferable at the center of the cornea, which is the location of the pupil 4. Care should be taken not to measure the IOP at the area of the Sclera 8, as the sclera tends to distort the measurement being thicker and tougher and less predictive than the cornea.

The system consists of two parts: an on-board subsystem that has an optical part 10 and an electro optical part 12, and an off-board part 22 that contains an electronic subsystem 24 and a pneumatic subsystem 28 and interface panel 29.

The optical subsystem 10 of the device is connected to an electro optical subsystem 12, and both are held in place by a structure that resembles the shape of eyeglasses, including a frame 14 supported by the nose 15 and an arm 16 supported by the ears 18. The structure holds the device in proximity to the eye, and protects the eye from a physical contact with the device. It should be noted that there could be alternative ways to maintain the optical subsystem in a stable and correct orientation with respect to the eye.

The off-board subsystem is connected with the on-board subsystem by an electric cable 26 and a pneumatic tube 30.

The device operates by sending a series of light pulses created by a light generator such as a laser diode or a light emitting diode (LED) located in the electro optical subsystem 12. The light pulses are conducted towards the eye through a light guide. The user is asked to direct his eyesight to a target within the device, ensuring that his cornea will face the incoming light. When the user is ready for the test and his eyesight is directed properly, he depresses a button

that triggers an air valve in the pneumatic subsystem 28. A pulse of compressed air is sent through the tube 30 and through the optical subsystem 10 onto the cornea. The cornea responds to the pressure of the air pulse by a slight retraction – affecting the amount of light reflected from the cornea into the optical subsystem 10. When the air pulse is stopped, the cornea tends to resume its original position, at a speed that is tightly linked to the internal ocular pressure. The dynamic changes in the shape of the cornea are affecting the dynamic light signal reflected from it into the optical system. A light detector in the elctro optical system detects the reflected light signal, and reports it to the electronic subsystem 24 thought he cable 26.

A microprocessor in the electronic subsystem analyzes the dynamics of the received signal and uses pre-determined tables or mathematical functions to determine the IOP.

The relationship between the dynamic reflection from the Cornea and the IOP is not described in much detail in this application, as it is well documented in the medical literature and is not materially different that the relationship used in large, clinic-based puff devices. Such function can be found in "Textbook of Glaucoma" by Bruce Shields edition 1998, published by Williams & Wilkins. The measurement can be repeated several times and averaged.

The gas in the pneumatic system can be clean air or an aerosol that has some medical significance such as IOP reduction medicine etc.

The device can be either mono or stereo, having one or two units.

Attention is now called to Figure 2.

Figure 2 describes the optical system and the electro optical system of the present invention. An eye 40 of a user is being tested for IOP by the system of the present invention. The IOP has to be measured in the area of the cornea 44, preferable at the center of the cornea, which is the location of the pupil 46.

The optical system comprises a pipe 48, which is positioned in front of the pupil at about 10 to 15 mm distance not to interfere with the eyelashes. The pipe 48 is a relatively thick wall pipe containing an inner tube 50. The face 52 of the pipe 48 is coated with a good anti-reflecting standard thin film coating. A second pipe 54 is connected to the inner tube 50 and is connected, on its other end, to the supply of compressed air (not shown). The connection between the tubes allows the compressed air to flow through the tube and towards the pupil 46.

The user, whose eye is schematically shown as 40 observes the reticule 76 though lens 78. The image 82 falls focused on the retina 42, using a second beam splitter 80 that lets the light beam flow with negligible loss.

The Electro-optical system comprises a light source 86 and detectors 74 and 72. Additionally it comprises the reticule 75 and an appropriate light source that illuminates it (not shown in the figure). Beam 60 is a light beam from a light source 86 or a collimated Light Emitting Diode. The beam is 60 is flowing through the tube 50 and impinges on the cornea in the area of the pupil 46. Some of the light is reflected from the cornea in the vicinity of the center of the pupil.

A beam splitting block 56 is attached to the tube 48 by an index matching glue or other compound (such as EPOTEC a commonly used optical glue). Optical surface 58 is the splits the beam 60 coming form the light source 86 into two components. One component is reflected by the optical surface 58 into the tube 50 and the second component continues through the optical surface 58 into a light detector 74. This light detector is used to monitor the light intensity of the light source and to stabilize through a feedback loop with the electric driver of the light source. Such stabilization is required both for the accuracy of the measurement and for safety of the eye.

The reflected beams - 62 and 64 - are captured by the tube face 52 and are guided by total internal reflection in the pipe 48 and through the beam splitting block 56 to the detector 72.

The Light beam is operated with the driver/ controller 84, which activates the light source 86 in pulsing mode. This light is preferably invisible, or hardly visible to the user to eliminate probable influence on the eye that might interfere with the measurement. When the user sees the reticule centered in the field of view he presses a button (not shown in the figure) and subsequently triggers the measurement process. The light is reflected from the cornea and is measured by the detector 72, which is connected to the electronic subsystem (not shown in the figure). The controller 84 instructs an air switch (not shown in this drawing) to release a pulse of compressed air into the tube 54 and then to the tube 50. The compressed air pulse deforms the curvature of the cornea, making it temporarily flatter, and at times even concave. The light illuminates the eye exactly where the cornea has been deformed by the air pulse. The changes in geometry of the cornea are translated into changes in the amount of reflected light that is captured by the face 52 of the pipe 48. This light is then detected by light detector 72, which translates the changes in light intensity into an electric signal. The electric signal, synchronized to the light pulses as detected in the light detector 74, are then sent to the processor 84 for analysis.

Attention is now called to Figures 3A to 3E.

Figure 3A depicts a train of pulses that describe the temporal intensity distribution of the light that is emitted from the light source. This is shown in

arbitrary units. The rate of the pulses as well as their duty cycle is controlled by the electronics system.

Figure 3B depicts a train of pulses at lower intensity that in Fig. 3A. This signal represents both the light that is reflected from the eye into the pipe 48 when there is no active air pulse, and light that reaches detector74 in Fig. 2.

Figure 3C shows the temporal intensity of airflow in the tube 50 on its way to the cornea.

Figure 3D shows the relative intensity of the light pulses as detected by the detector 72, following the effect of the air pulse of figure 3C on the Cornea. The case where the light source is not collinear with the eye axis is well described in the literature such as in the Textbook of Glaucoma by Bruce Shields 4th edition 1998 published by Williams and Wilkins page 62-63. The situation where the light source is collinear with the eye axis as it is in our case is explained in Figure 3d – Figure 3E. Pulses 90 show the relative intensity of the reflected light prior to the effect of the air pulse. They are equal in intensity and generally weak relatively to the forthcoming pulses. As the leading edge 92 of the air pulse begins to flatten the cornea, the reflected pulses grow stronger, as a larger part of the reflected light enters the pipe 48. This increase is shown in pulse 96. As the cornea continues to be effected by the air pulse and begins to be concave, the light intensity decreases 98. As the cornea becomes more concave, it assumes the shape of a concave mirror and causes some of the reflected light to enter the outer areas of the pipe 48. This causes an increase in the light intensity, as seen in [pulse 100. As the cornea becomes even more concave, the reflected light from the concave mirror focuses at the center of the pipe 48, entering the area of the hollow tube 50. Light captured in the hollow tube 50 will never reach the detector 72 and therefore there is an decrease in light intensity – as seen in pulse 104. The situation will prevail, and more light pulses similar to 104 will be reflected, until the air pulse is stopped (108) and the cornea rapidly resumes its stationary convex situation. On its way from the concave to the convex position, the cornea passes through a similar sequence of states, in a reversed order. When it is flat again, the reflection of light in to the pipe 48 is maximal, and a strong light pulse 106 is detected by the detector. When the corneas finally stabilizes in its steady convex state, the light pulses are weak again 112, and are similar to those prior to the air pulse. There may be another small peak of reflection when the cornea passes through the "concave mirror" state as described above – however this is not used in the present invention and is also not fully described in the literature, so this drawing should be regarded as a partial description of the dynamic process – sufficient for a full disclosure and understanding of the present invention.

Figure 3E shows a linear approximation of the amplitude pattern of the reflected light, as detected in the light detector 72. The main significant events are shown as the apexes of the chart as follows:

T1 is the time when the air pulse begins to be observed in the light pulse amplitude.

B1 is the relative intensity of the reflected light at time T1

T2 is the time of the peak light amplitude, representing the flat ingoing cornea.

B2 is the relative intensity of the reflected light at time T2

T3 is the time of the minimum reflected light, when the cornea begins to be concave but not yet reflects a lot of light into the pipe.

B3 is the relative intensity of the reflected light at time T3

T4 is the time when the cornea has the concave geometry that sends a lot of light into the outer sleeve of pipe 48.

B4 is the relative intensity of the reflected light at time T4

T5 is the time when the reflected light is minimal, due to the focusing of the light into the inner tube 50 of the pipe 48 by the very concave cornea.

B5 is the relative intensity of the reflected light at time T5

T6 is the time when the cornea is flat again on its outgoing way, after the air pulse has been terminated.

B6 is the relative intensity of the reflected light at time T6

T7 is the time when the effect of the air pulse on the cornea is over, and the cornea is in the same state as in T1.

The relative intensity of the reflected light at time T7

The numbers T1-T7 and B1-B7 are the data that is used by the processor to compute the IOP. Specifically, the slope of the post-pulse chart defined as (B7-B6)/(T7-T6), are correlated in the literature directly with the IOP. The other parameters of 3E are also influenced by the IOP and mechanical condition of the eye under test, and their significance will be quantified through statistics and clinical tests to be conducted with the device of this invention.

Attention is now called to Figure 4

Fig. 4 describes the electronics system interface with the rest of the system, controlled by a processor 136.

The display 120 displays the results of the measurements. It can be a simple 7-segment display device or a LED/LCD matrix display. The buzzer 122 is a device that makes an audible sound when the attention of the user has to be called to the display. This will happen if the measurement fails, or if the battery is low, etc.

The air bottle valve 124 operates on a command from the processor 136, to release a measured air pulse air into the system.

A safety air pressure gauge 136 is used in the air release system, to stop the airflow if it exceeds the specified limits of flow or duration. This gauge is also instrumental for notifying the user that the air bottle is empty and needs replacement.

The light source driver 126 activates the light source upon a command from the microcomputer and sends a beam of light as a train of pulses to the eye. The driver uses feedback from the detector 74 to maintain a sable, controlled light intensity.

The reticule lamp 128 illuminates an optical target 76 that is used by the system of this invention to direct the eyesight of the user in line with the tube 50. The user is asked to direct their eyesight to the reticule, and to indicate when they are ready for the measurement.

The trigger button 130 is the input device of the user to the computer.

The reference detector circuit 132 processes the information from the reference detector 74.

The signal detector circuit 134 picks up the information from the detector 72, triggered by the reference signal created at the reference detector circuit. The reference trigger enables this circuit to detect very weak signals and thus be very sensitive.

Attention is now called to Figure 5

This figure shows a general view of a preferred embodiment of the device, having dual measurement systems to measure both eyes. The measurement cannot be done simultaneously, but as the orientation of the tube 48 to the eye has to be very accurate and customized to every patient – there may be a different orientation for each eye, thus requiring a dual installation. This can be achieved more economically, by providing a frame that has two adjustable mechanical holders, adjusted for the specific eyes of the user, and having the active part of the system alternating between the two holders.

-End -

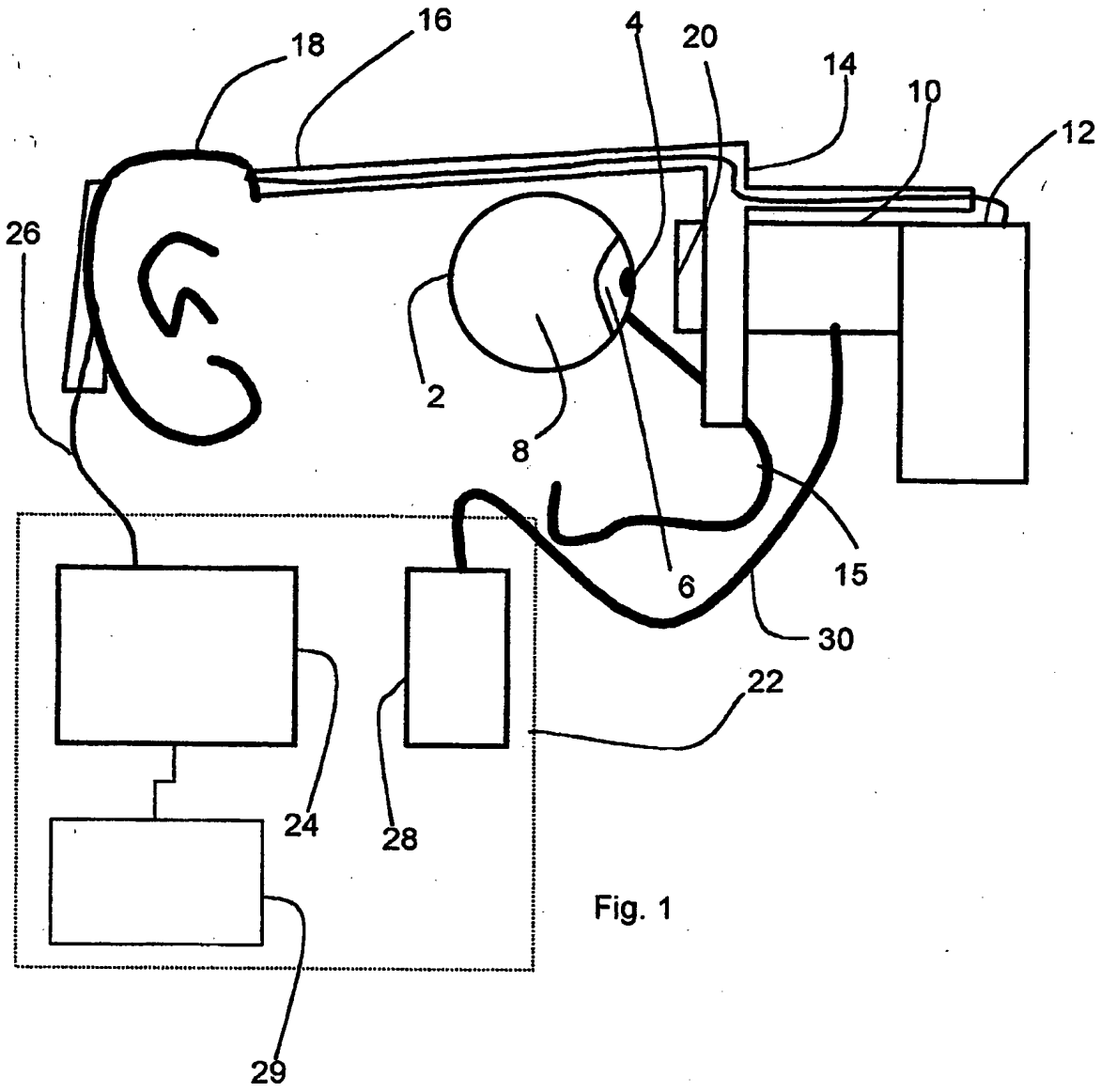

Fig. 1

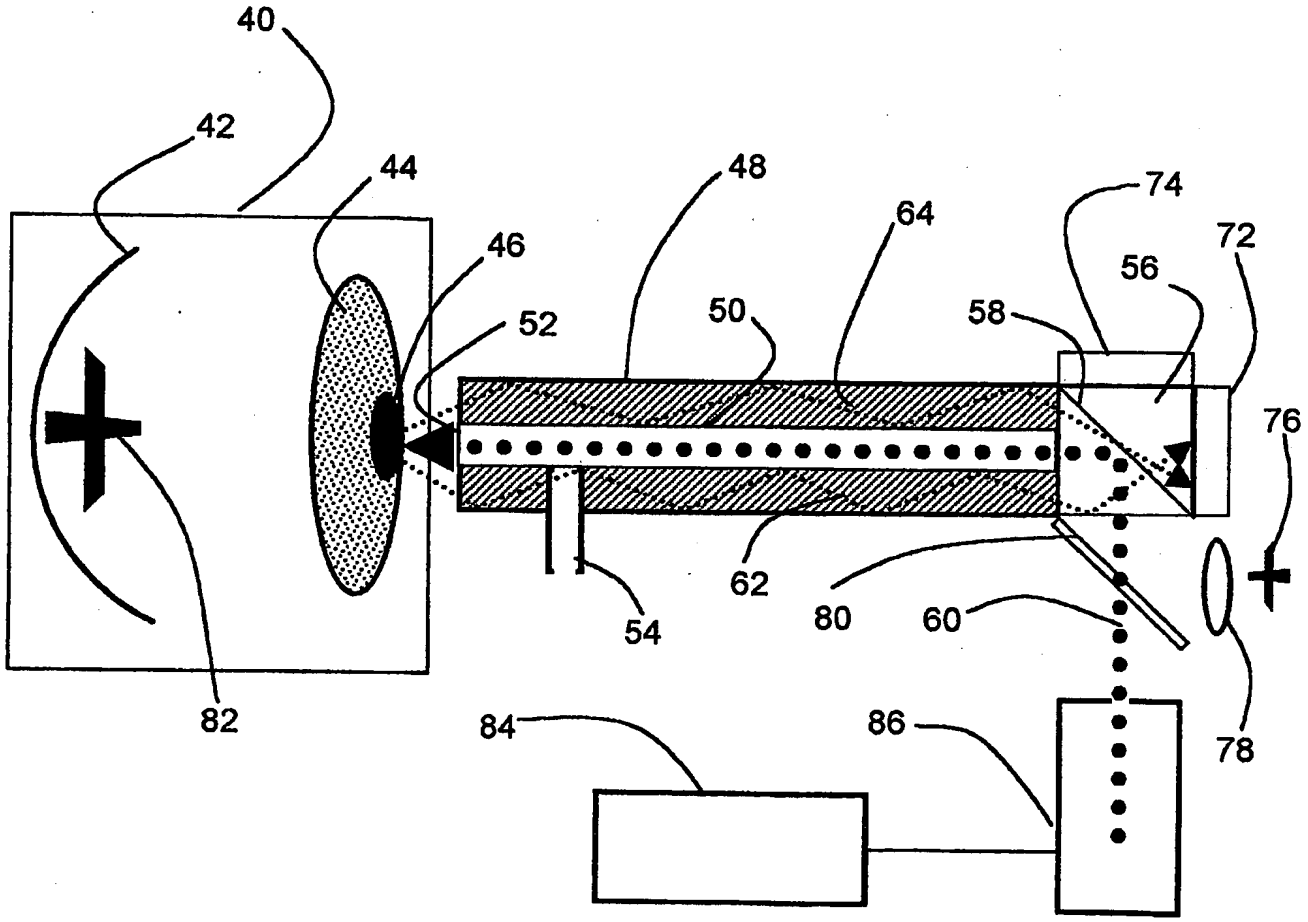

Fig. 2

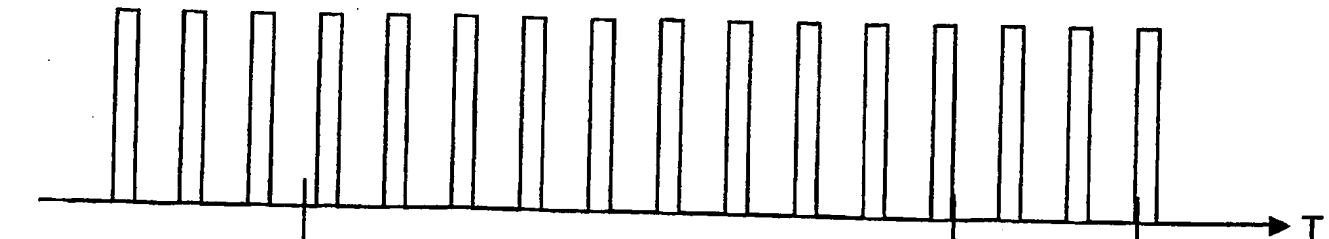

Fig. 3A

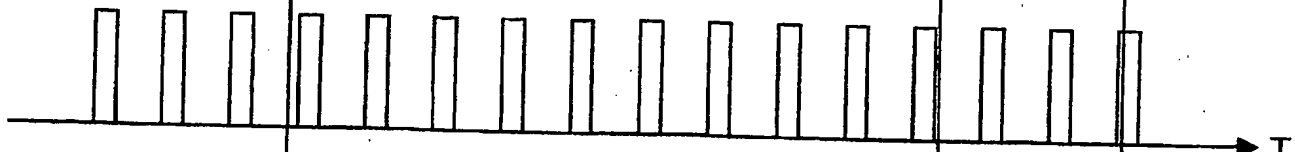

Fig. 3B

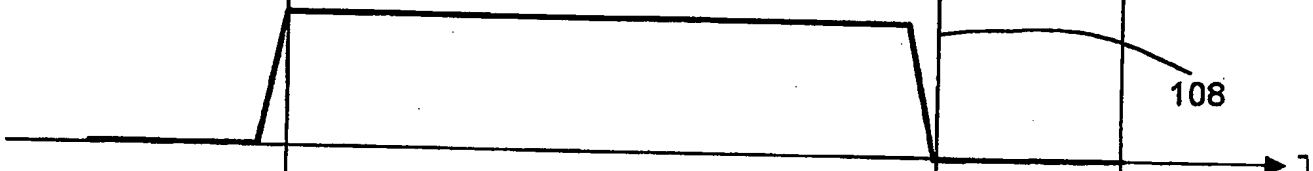

Fig. 3C

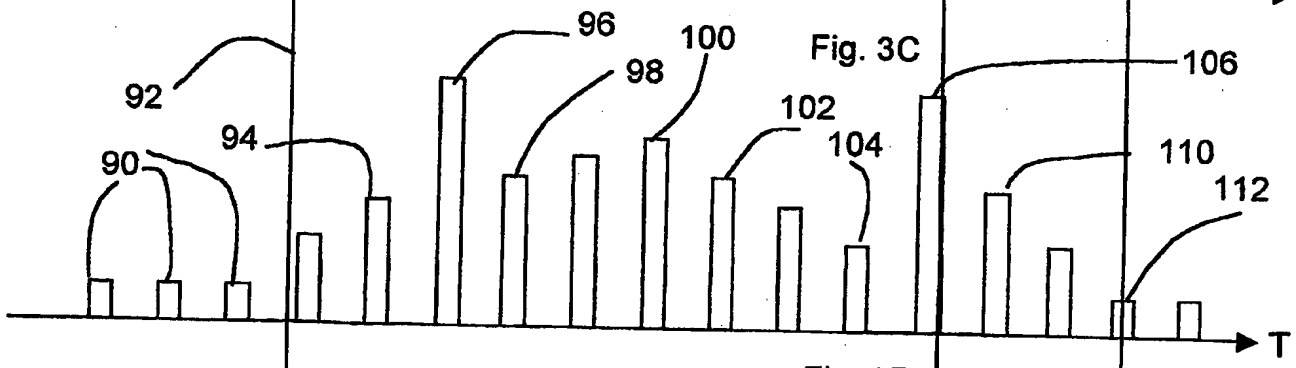

Fig. 3D

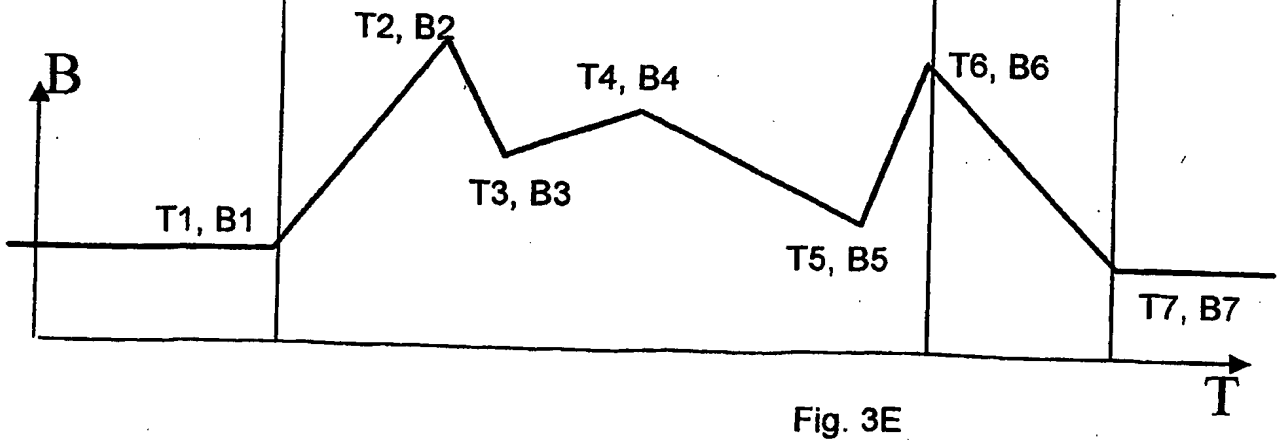

Fig. 3E

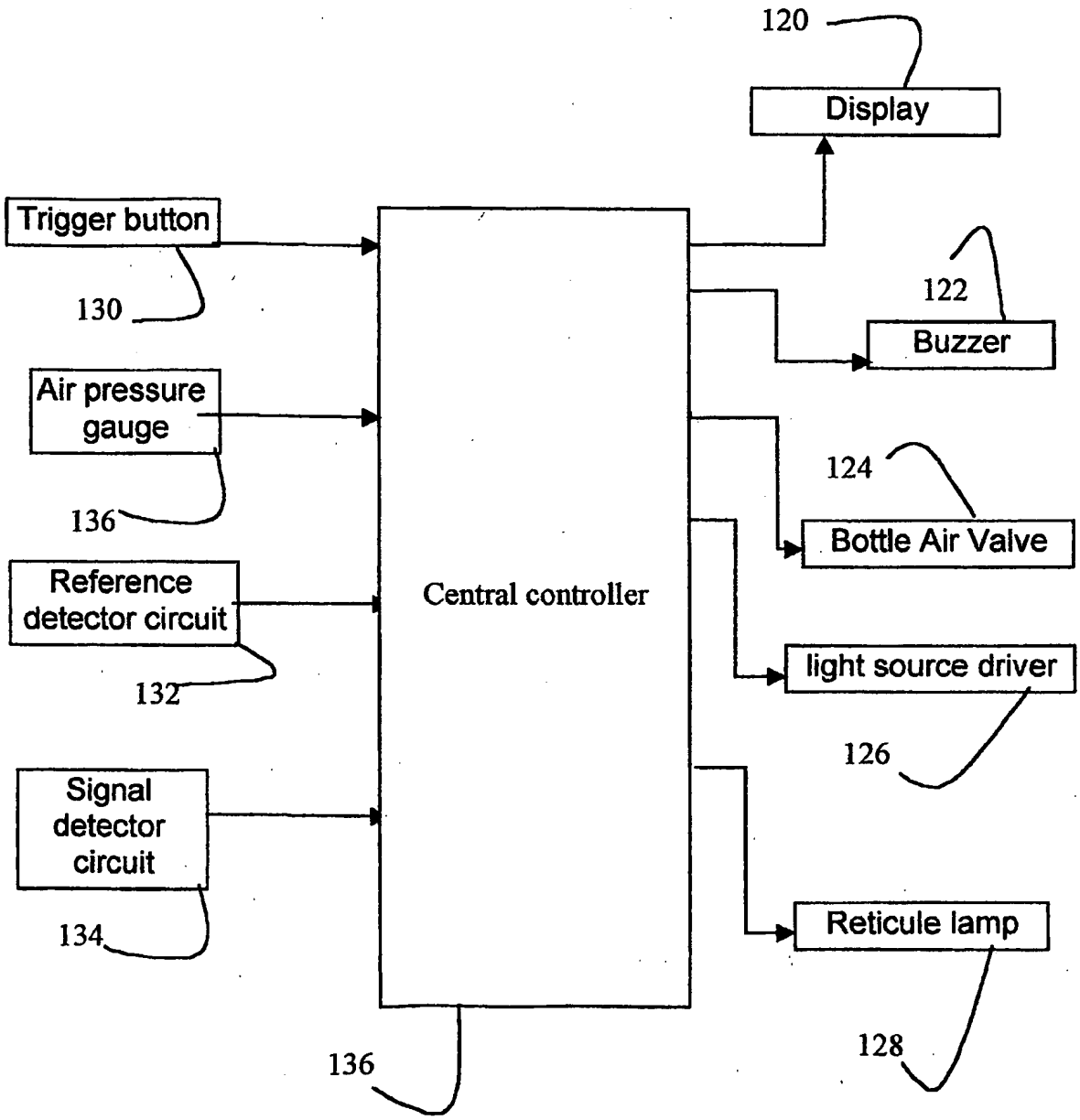

Fig. 4

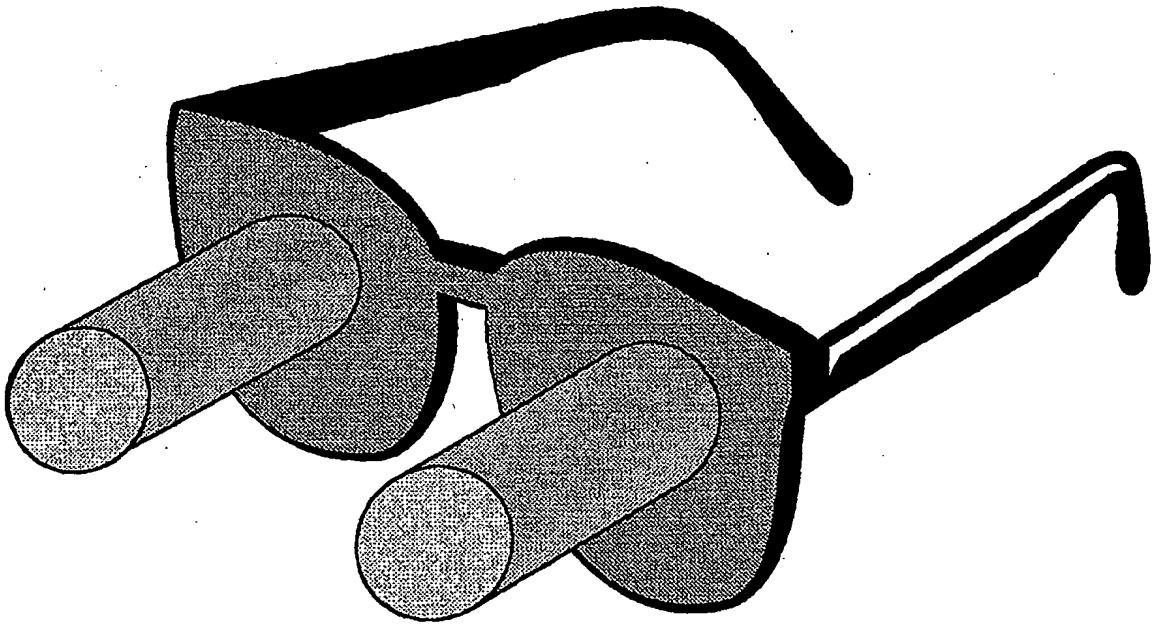

Fig. 5